

### REMARKS/ARGUMENTS

In the above amendment to Claims 1, 16, & 17, the words bioadhesive and bioadherent have been added. Support for the amendment may be found throughout the Specification, and specifically at page 4, line 24; page 8, line 5; page 9, line 35; page 10, line 7; page 11, line 23 and page 18, line 27.

In the above-identified Office Action the Examiner has rejected Claims 1-8, 10-11, 16-18 under 37 USC 102(b) as anticipated by Morrissey et al. (US 6,106,820). Applicant respectfully disagrees. Morrissey discloses a polymer with a hydrophobic main chain (Tg between 0 and 50° C. and hydrophilic side chains (column 4, lines 29-31.) Applicant's polymer has a hydrophilic backbone and hydrophobic polystyrene homopolymer side chains. Hence applicant submits that its compositions, as described in Claims 1, 11, 16 & 17, or Claims 2-8, 10, and 18, dependent therefrom, having a hydrophilic main chain and hydrophobic polymer side chains, are not anticipated by, nor rendered obvious from, Morrissey et al.

In the above-identified Office Action the Examiner has also rejected Claims 1-4, 6-8, 10-11, 16-17 under 37 USC 103(a) as unpatentable over Shah (5,942,243). Shah discloses a mucoadhesive delivery system comprising the same graft copolymer has those of the present application. The mucoadhesive delivery system forms a water-swollen but water-insoluble jelly like mass upon contact with the biological environment, and is characterized, generally, by extensive hydration and formation of a hydrogel in an aqueous environment. The disclosure of the mucoadhesive characteristic of the delivery system does not indicate whether or not the film forming composition of the present invention will adhere to the skin (page 5, lines 14-16 of the present application). For instance, it is well recognized by those skilled in the art of dermatological product formulations that the mucoadhesive water soluble or water-swellaable polymers, described and used in the below cited mucosal product applications, do not perform suitably on skin in terms of wear time or retention on it.

1. Mucoadhesive: sodium carboxymethyl cellulose:

- A. Colgate Orabase paste or gel formulas with 20% Benzocaine provide fast, temporary relief from pain associated with canker sores, and oral irritations. Shields from further irritations.

Inactive Ingredients: Cellulose Gum (*sodium carboxymethyl cellulose*), Flavor, Guar Gum, Pectin, Plasticized Hydrocarbon Gel, Preservatives, Xanthan Gum

B. ConvaTec (Bristol Myers Squibb Company) Orabase paste adheres tenaciously and remains in intimate contact with mucous membranes of the mouth and gums, protecting the afflicted area in the mouth against further irritation from chewing, swallowing and other normal mouth activity. Orabase is composed of gelatin, pectin and sodium carboxymethylcellulose in Plastibase plasticised hydrocarbon gel).

2. Mucoadhesive : Hydroxypropyl cellulose: hydroxypropyl cellulose coating for Adhesive tablet for buccal or sublingual administration. Schor, J.M., et al., Drug Dev. Ind. Pharm., 9, 1359, 1983.

3. Mucoadhesive : Hydroxypropylcellulose and carbopol (cross-linked sodium polyacrylic acid). Mucosal dosage form (gel) of lidocaine for toothache using hydroxypropylcellulose and carbopol (cross-linked sodium polyacrylic acid). Ishida, M., Chem.Pharm. Bull., 31, 980, 1982.

None of these water soluble or water-swellaable mucoadhesive compositions when formulated in aqueous carriers, and applied to the skin would be expected to produce the adequate retention on skin, but will instead dry, flake, peel.

Similar problems are encountered with most water soluble and water swellaable polymers. There are significant challenges to the actual creation of a bioadherent film. Skin is living substrate. It breathes, perspires, stretches and contracts. For a film to be bioadherent, it must do the same, and accommodate the various functions of the skin during different body activities, during various environmental conditions such as temperature and humidity. One may infer that in order for the formed polymeric film to be bioadherent it must have the viscoelastic properties, breathability, and moisture vapor permeability properties that are similar to skin. Otherwise it will feel uncomfortable or tight, and will tend to peel and flakes during use, yielding inadequate wear time and loss of efficacy. Retention of the formed polymeric film on skin for the desired duration of time is a common problem that is encountered in developing bioadherent films. The film forming compositions of the present invention are highly skin retentive, as may be noted in the various examples set forth in the present application.

As noted in the present application, at page 8, lines 23-33, though the copolymer is insoluble in water, it forms a very stable, homogenous gel under high energy mixing, as with a homogenizer. Though an opaque dispersion of fragmented gel particles was anticipated (which would not be expected to form a bioadherent film), a clear gel with a bluish haze was produced by homogenizing the copolymer, indicating submicron size particles, and raising the possibility of a forming a bioadherent film. This homogenized composition is set forth in Claim 11.

Lastly, in the above-identified Office Action the Examiner has rejected Claims 1-8, 10-11, 16-18 under 37 USC 103(a) as unpatentable over Shah (5,942,243) in view of Morrissey et al. (US 6,106,820). As stated above, Claims 1, 11, 16 & 17, and Claims 2-8, 10 and 18, dependent thereon, are not anticipated by, nor rendered obvious from Morrissey et al. As the chemical structures of the two references are opposites, in that the backbone of Morrissey is hydrophobic while the backbone of Shah is hydrophilic, and the side chains of Morrissey hydrophilic while the side chains of Shah are hydrophobic, Applicant is unclear how the Examiner combines Morrissey with Shah. Indeed, it would seem that Shah does not meet the deficiencies of the Morrissey reference in rendering obvious the present invention, but counters Morrissey, leaving simply the original references discussed above.

Applicant respectfully requests that a timely Notice of allowance be issued in this case. Should the Examiner has any question regarding the above, or believes that it would advance the prosecution of the application, he is asked to telephone Applicant's attorney at (973) 761-0714.

Respectfully submitted,



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